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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,862	12/10/2003	Katclynn Lyons	ICC-136.0 (4564/88881)	9117
24628	7590	05/15/2007		
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			EXAMINER PENG, BO	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,862

Applicant(s)

LYONS ET AL.

Examiner

Bo Peng

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed March 6, 2007. Claims 1-46 are pending and considered in this Office action.

2. The rejection of Claims 1-46 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over (1) claims 1-78 of 09/930,915; (2) Claims 1-53 of 10/787,734; (3) Claims 98-109 of 10/805,913 and Claims 79-115 of 10/806,006, **is maintained**.

Applicant acknowledges the rejection and does not wish to prematurely respond.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1-46 under 35 U.S.C. § 112, first paragraph, for containing new matter, **is maintained**.

5. Applicant argues that the support for specification has for "said chimera molecule containing up to about 5 percent conservatively substituted amino acid residues in the HBc sequence relative to SEQ ID NO: 1," in Claims 1, 11 and 25 can be found in specification paragraph [0231][0232][0233].

6. Applicant's argument is considered but found not convincing because none of cited paragraphs teaches "said chimera molecule containing up to about 5 percent conservatively

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substituted amino acid residues in the HBc sequence relative to SEQ ID NO: 1". Specifically, [0231] mentions conservative substitution in HBc, but does not have % limitation. [0232] does not teach any thing about substitution. [0233] teaches 20%, 5% to 3% substitution in SEQ ID NO:1, but not the new limitation of 5 percent conservatively substitution.

7. Removal of all new matter is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of Claims 1-6, 8-14, 16-28, 30-42 and 46 under 35 U.S.C. 103(a), as being unpatentable over Pumpens, in view of Zlotnick and Zhang, is **maintained** for the reasons of record.

10. Applicant argues that the specification shows that C-terminally stabilized C48S/C107S chimera appeared to be entirely disulfide bonded at day zero, whereas its C48/C107 counterpart was not and did not reach the same level of cross-linking achieved by the C48S/C107S chimera during the period of study [0525]. Thus, Those results were intuitively unexpected and even more unexpected from the reading of Zheng in conjunction with Zlotnick.

11. Applicant's argument is considered but found not persuasive because Zlotnick teaches that C-terminal Cys can stabilize HBcΔ, and Zheng teaches that Cys48 and Cys107 are not essential for native core particle formation. Thus, one of ordinary skill in the art would

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recognize that replacing unnecessary Cys48 and Cys107 with other amino acid residues could facilitate Cys61 and C-terminal Cys to form inter-chain disulfide bonds with the identical residues of another monomer. Since Zlotnick and Zhang have taught the function of C-terminal Cys, Cys48 and Cys107, one of ordinary skill in the art is capable to correctly apply such knowledge in the design of an HBc Δ chimera.

12. The rejection of Claims 1-6, 8-28, and 30-46 under 35 U.S.C. 103(a), as being unpatentable over Page and Birkett, both in view of Zhang, is **maintained** for the reasons of record.

13. Applicant argues that although Zheng provides a suggestion of enhanced stability because of the presence of one or both Cys residues at positions 48 and 107, the inventors here found that the particles formed are more stable without those presumably stabilizing residues. Thus, the claimed result is unexpected.

14. In response, the claimed result is not unexpected because the cited references have provided specific teaching about the role Cys48, Cys107 and C-terminal Cys in forming an HBc particles, see discussion in Paragraph 11, one of ordinary skill in the art is capable to correctly apply such knowledge in the design of an HBc Δ chimera.

15. Applicant's attention is invited to the Paragraph 32, Non-final office action mailed on November 17, 2006, in which the Examiner indicated that Claims 7, 15 and 29 are free of the prior art. Claims 7, 15 and 29 are objected as being dependent from the rejected claims.

Applicant fails to respond to the objection.

Remarks

16. No claim is allowed. THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Bo Peng, Ph.D.
May 3, 2007


BRUCE R. CAMPPELL, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600